User's Manual

VENTILATION
SERVO-i/s
CLEANING AND MAINTENANCE

MAQUET

CRITICAL CARE

TABLE OF CONTENTS

1 Introduction | 5
2 Routine cleaning | 9
3 Maintenance | 27

1 INTRODUCTION

TABLE OF CONTENTS

1.1	Introduction	|	6
1.2	Warnings, Cautions, and Important	|	6
1.3	Symbols	|	6
1.4	General information	|	6
1.5	Wall diagrams	|	7

1.1 INTRODUCTION

Unless otherwise stated, the information in this User´s Manual is valid for all SERVO-i/s Ventilator Systems.

Here you will find the information needed to clean and maintain the SERVO-i/s systems safely. The manual is divided into three sections:

- Introduction (mandatory information)
- Routine cleaning
- Maintenance

Instructions relevant only for either SERVO-i or SERVO-s are marked. Parts included in SERVO-i only:

- Battery module
- Y sensor
- CO_2 sensor
- Edi module

1.2 WARNINGS, CAUTIONS, AND IMPORTANT

WARNING! Indicates critical information about a potential serious outcome to the patient or the user.

Caution: Indicates instructions that must be followed in order to ensure the proper operation of the equipment.

IMPORTANT: Indicates information intended to help you operate the equipment or its connected devices easily and conveniently.

1.3 SYMBOLS

Hazardous waste The device contains parts which must not be disposed of with ordinary waste.

1.4 GENERAL INFORMATION

As cleaning practices vary widely among health care institutions, it is not possible for MAQUET to specify particular practices that will meet all needs, or to be responsible for the effectiveness of cleaning procedures carried out in the patient care setting.

MAQUET recommends methods that have been validated using the specified equipment and procedures outlined in this manual. Other methods may work but are not covered by the warranty unless MAQUET has given written permission.

Cautions:

- All personnel should be aware of the risk of parts being infected when disassembling and cleaning the ventilator.
- All disposable parts must be discarded according to hospital routines and in an environmentally safe way.

IMPORTANT:

- Follow your hospital‘s guidelines for handling infectious material when handling any part of the SERVO-i/s ventilator system.
- If possible, cleaning should be performed immediately after use and always before disinfection/sterilization. Blood or other residues should not be allowed to dry onto the devices.
- Water quality affects cleaning/disinfection. MAQUET recommends drinking quality water as the minimum quality level.
- MAQUET recommends the use of Servo Duo Guard bacterial filter or equivalent to reduce the transmission of bacteria from the patient via the expiratory channel to the expiratory cassette. This reduces the risk of infection spread and prolongs the life of the expiratory cassette due to reduced cleaning requirements.
- The use of a washer-disinfector for cleaning/disinfection is recommended if bacterial filters are not used.
- Sterilization is normally not necessary for the expiratory cassette, as it is not an invasive instrument, but when applied, use validated processes only.

1.5 WALL DIAGRAMS

The wall diagrams are provided as checklists and contain overviews and step-by-step instructions for cleaning, to be posted on a wall.

2 ROUTINE CLEANING

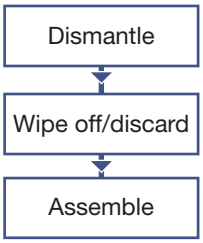
TABLE OF CONTENTS

2.1	Cleaning/disinfection procedures - a summary	10
2.2	Preparations and dismantling	12
2.3	Wiping and discarding	14
2.4	Disinfection procedures	16
2.5	Sterilization procedures (not recommended)	19
2.6	Assembling	20
2.7	SERVO Ultra Nebulizer cleaning	21
2.8	SERVO-i NAVA system cleaning	23
2.9	SERVO CO_2 analyzer cleaning	24
2.10	Accessories	26

2.1 CLEANING/DISINFECTION PROCEDURES - A SUMMARY

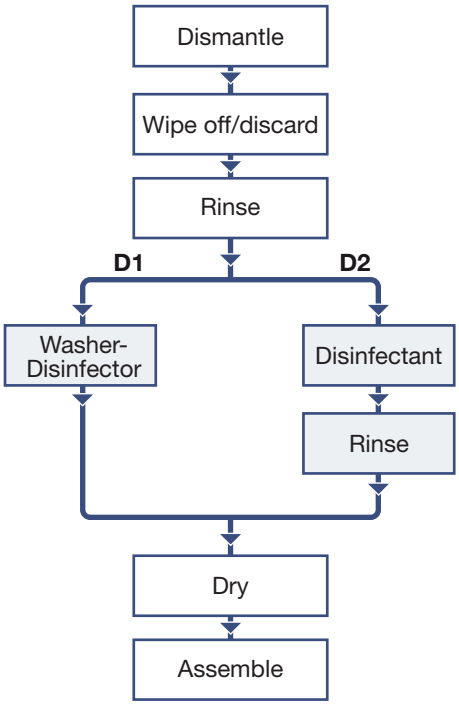
A summary of the procedures for cleaning, disinfection and sterilization is given here. Details for each step are given in the following sections.

Cleaning when bacterial filter is used



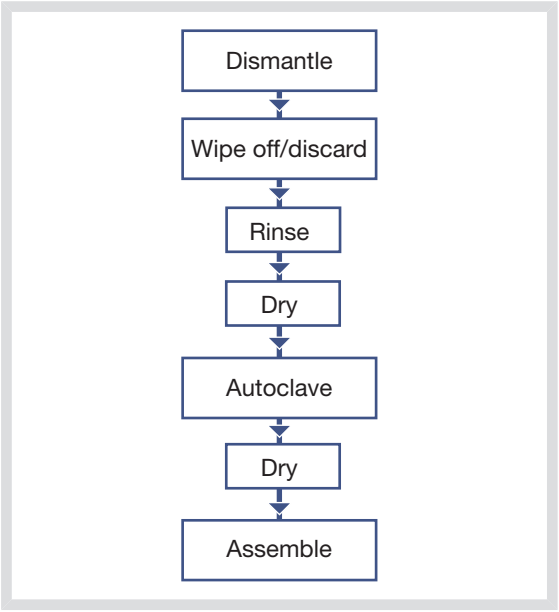
Wipe off and discard filter, see page 14.

Disinfection when no bacterial filter is used



There are two disinfection procedures for the expiratory cassette and associated parts, D1 and D2. In D1 (recommended) a Washer-Disinfector (EN-ISO-15883-1) is used, and in D2 a disinfectant is used.

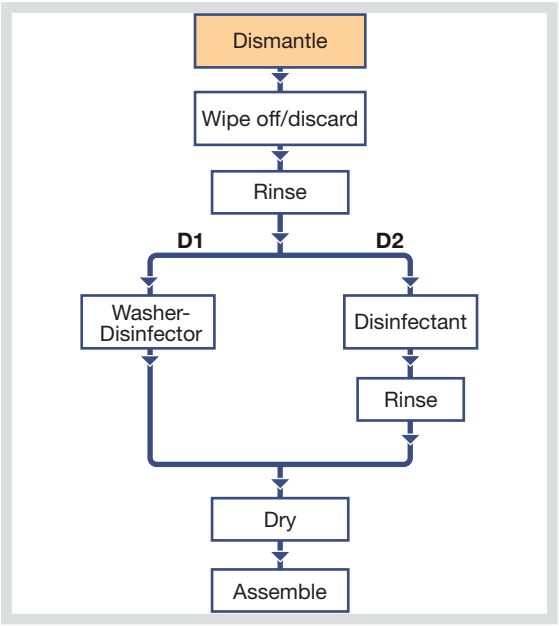
Sterilization with autoclave (NOT recommended)



Autoclaving will reduce the lifetime of the expiratory cassette and is not recommend as a cleaning method.

Sterilization is normally not necessary for the expiratory cassette, as it is not an invasive instrument, but when applied, use validated processes only. See further instructions about autoclaving on page 19.

2.2 PREPARATIONS AND DISMANTLING

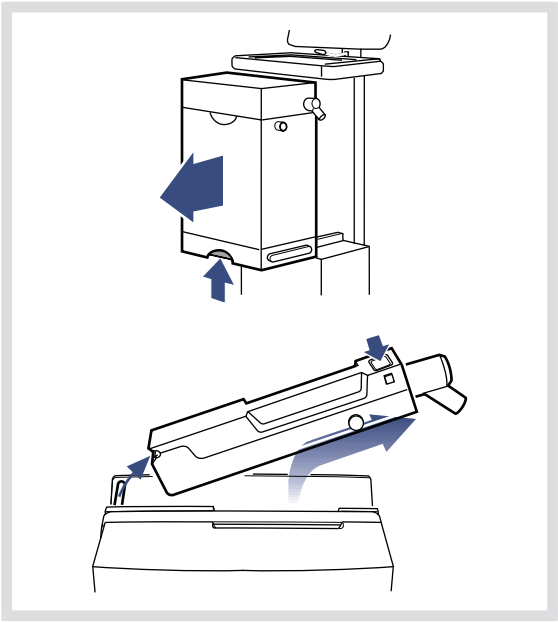


2.2.1 PREPARATIONS

- Switch off the ventilator using the switch on the rear of the User Interface.
- Disconnect the ventilator from the power and gas supply.
- Disconnect any optional equipment from the power supply and from the ventilator.

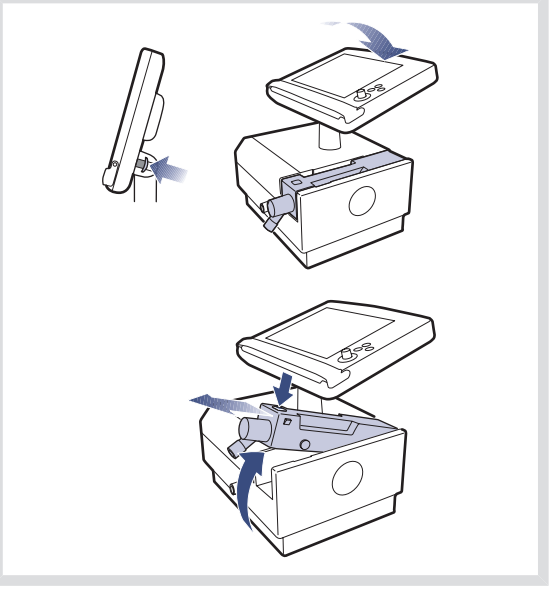
2.2.2 REMOVE THE EXPIRATORY CASSETTE

SERVO-i



- Lift the locking handle and pull out the patient unit.
- Press the button on the expiratory cassette, tilt it upwards and remove.

SERVO-s



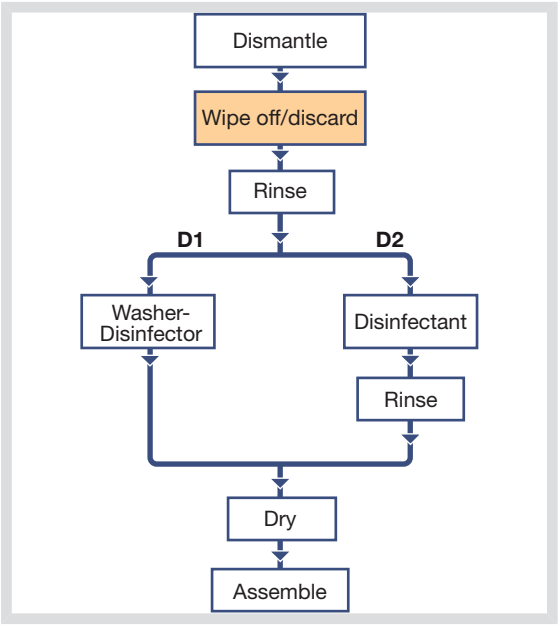
- Press the locking arm on the rear to tilt the User Interface.
- Press the button on the expiratory cassette, tilt it upwards and remove.

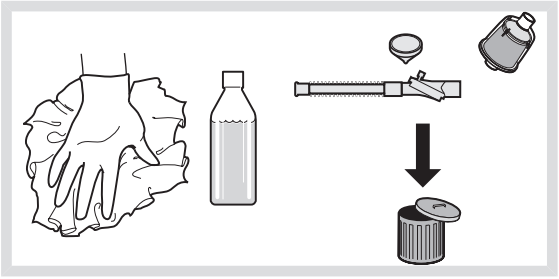
WARNING! After removing the expiratory cassette, do not pour any fluid into the expiratory cassette compartment. Avoid contact with electrical connectors.

IMPORTANT: The expiratory cassette can be exchanged between different SERVO-i/s ventilator systems. The ventilator may be used immediately* by connecting a clean expiratory cassette.

* After replacing the expiratory cassette, a Pre-use check must be performed (except in emergencies, when it should be performed as soon as possible).

2.3 WIPING AND DISCARDING





1. Wipe the ventilator and all removable parts with a soft lint-free cloth moistened in soap & water or detergent-based disinfectant.

Note: In case of more contaminated surfaces, use ethyl alcohol (70%) or isopropyl alcohol (70%). Avoid contact with electrical contacts.

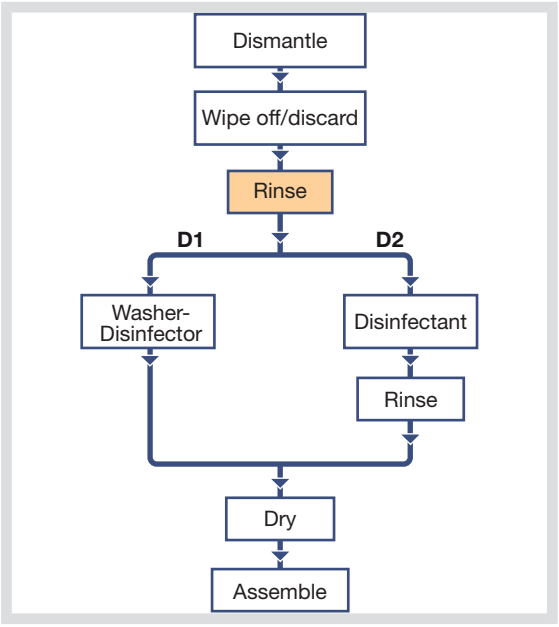
Caution: Do not immerse battery, CO_2 analyzer, or Y sensor module (SERVO-i only) in any fluid.

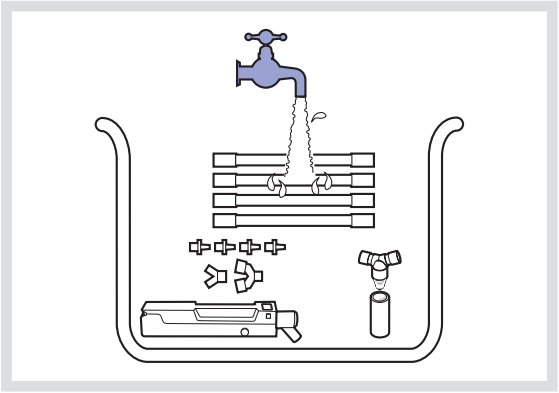
2. Discard disposable items:
- Servo Duo Guard viral/bacterial filter
- Servo Humidifier/HME
- Y sensors (SERVO-i only)
- disposable patient tubing

Regularly check that the fan filter looks clean (i.e. black). If dusty, remove (snap off/snap on) and rinse in water. Shake out, ensuring that the filter is free from excess water.

This is all the cleaning that is required when a Servo Duo Guard filter (or equivalent) is used.

2.3.1 RINSE BEFORE DISINFECTION





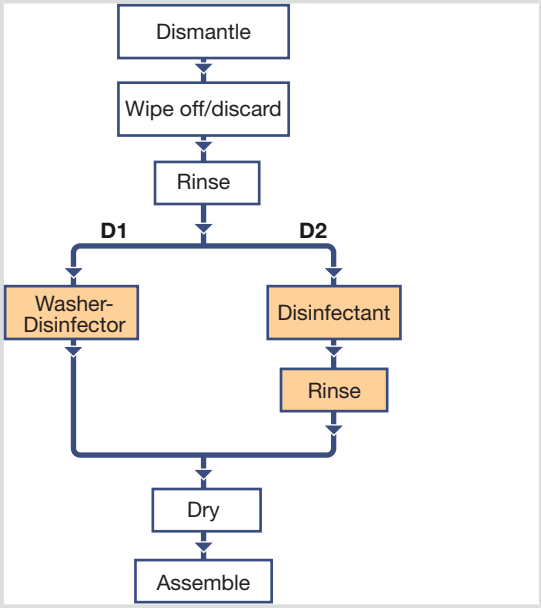
If rinsing before disinfection is not included in the washer disinfector program:

- Rinse the parts thoroughly in water (<35°C/95°F).
- Let the water flow through the parts.

IMPORTANT: Rinsing the cassette in water (<35°C/95°F) immediately after use may be a useful alternative to disinfection. Immediate rinsing can remove particles and reduces the risk of cross-contamination between patients.

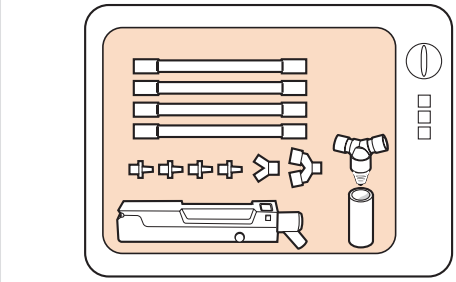
2.4 DISINFECTION PROCEDURES

2.4.1 WASHER-DISINFECTOR (D1)

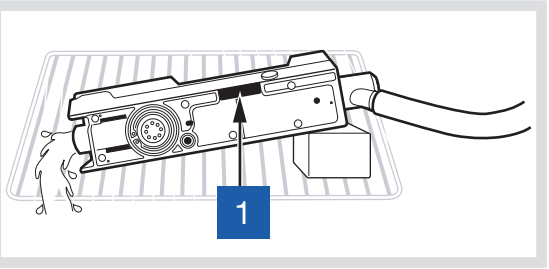


IMPORTANT:

- The expiratory cassette is a precision instrument and must be handled carefully.
- After disinfection procedure, all parts must be dried before use. If the expiratory cassette is not dry it may not pass the Pre-use check.



- Wash the parts with water only in a washer-disinfector at a temperature of 85-95°C (185-203°F).

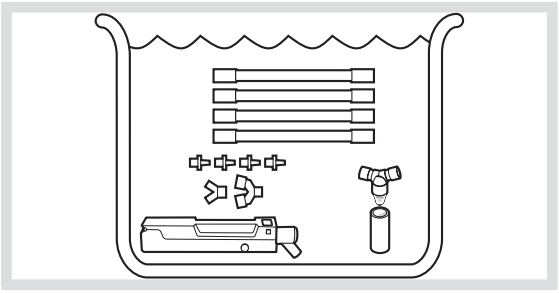


- Place the expiratory cassette on its side with the electrical connector (1) uppermost as shown in the picture above.

Notes:

- The water pressure in the washer-disinfector should not exceed 1.5 bar.
- The maximum water flow should not exceed 10 l/min.
- The water must have free passage through the cassette.

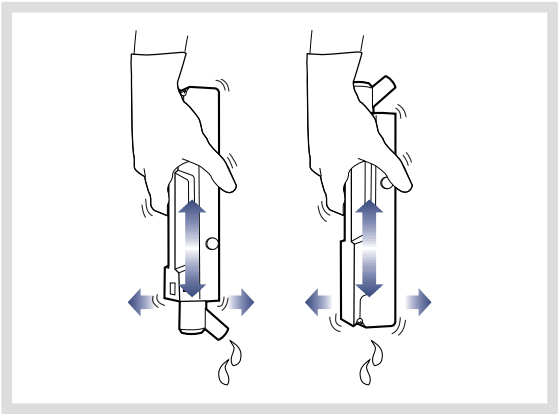
2.4.2 DISINFECTANT (D2)



Let the parts soak in disinfectant such as
- Alcohol (ethyl or isopropyl alcohol 70%)
- Cidex OPA
- Hexanios G+R
- Aniosyme DD1
- Gigazyme Plus
- Anioxyde 1000

IMPORTANT: Follow the disinfectant manufacturer's recommendations and instructions, otherwise the cassette may be damaged.

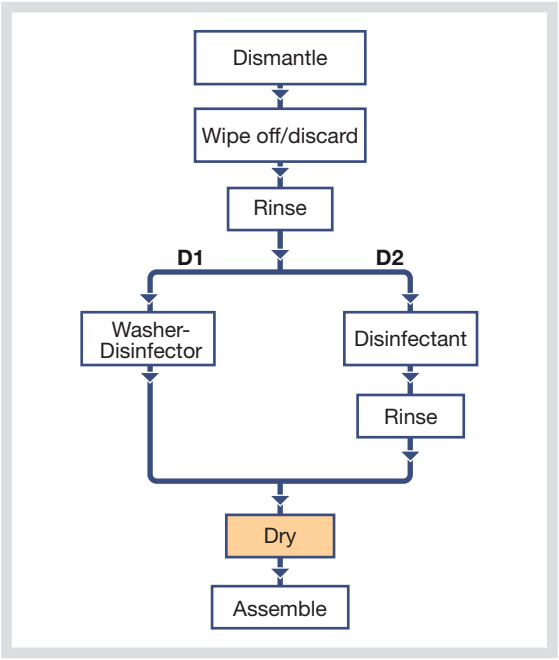
2.4.3 RINSE AFTER DISINFECTION (D2)



- Rinse the parts thoroughly in water to remove all traces of disinfectant. Let the water flow through the parts.
- **Carefully** shake and tilt the cassette, turn upside down and repeat.
- Repeat these steps at least 5-7 times.

IMPORTANT: Mineral deposits from disinfectant on the expiratory cassette affect the function. It is important to rinse the expiratory cassette thoroughly. Residues from chemicals can affect the patient, cause leakage and extra stress on the material.

2.4.4 DRYING ALTERNATIVES

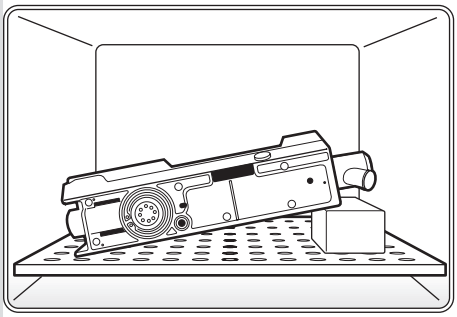


The expiratory cassette must be dried before use (if not dry, the expiratory cassette may not pass the Pre-use check).

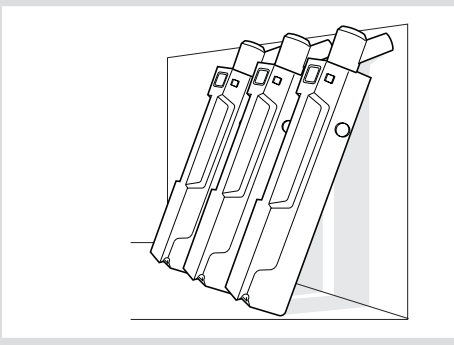
There are several drying alternatives for the expiratory cassette:

- Carefully shake/tilt the cassette (5-7 times), or
- Drying cabinet 1 hour in maximum 70°C (158°F); if available, connect a 22 mm air hose to the expiratory cassette for extra drying effect.

Recommended position in a drying cabinet



Recommended position in room air



If the Pre-use check is not passed after drying then:

- Run the cassette in a SERVO-i/s ventilator with a test lung for 10 minutes, or
- Dry the cassette in room air (if no drying cabinet is available) 12-24 hours, depending on surrounding conditions.

Caution: Never dry the cassette by applying high-pressure air as the internal tubing may be damaged.

Note: Drying may not be necessary if the washer-disinfector has a drying phase.

2.5 STERILIZATION PROCEDURES (NOT RECOMMENDED)

An autoclave may be used to sterilize the expiratory cassette but it is normally not necessary, as the expiratory cassette is not an invasive instrument.

2.5.1 NUMBER OF CYCLES IN THE AUTOCLAVE

The expiratory cassette will last at least:

- 100 autoclaving cycles with 4-7 minutes sterilization time at 134ºC (273ºF).
- 50 autoclaving cycles with 18 minutes sterilization time at 134ºC (273ºF).

2.5.2 RINSE

Rinse the parts thoroughly in water (<35°C/95°F). Let the water flow through the parts to remove organic matter, e.g. blood, and other residues.

2.5.3 DRYING BEFORE AUTOCLAVING

Before placing the expiratory cassette in an autoclave, make sure that no water remains inside the cassette. For drying instructions, see page 18.

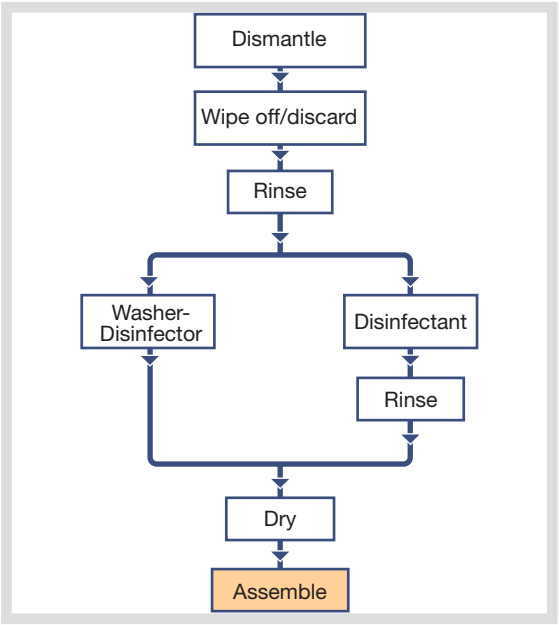
2.5.4 AUTOCLAVE

- Instrument parts should be autoclaved in a validated process, typically at a temperature of 134°C (273°F) for 4-7 minutes.
- Rubber parts should be autoclaved in a validated process, typically at a temperature of 121°C (250°F).

2.5.5 DRYING AFTER AUTOCLAVING

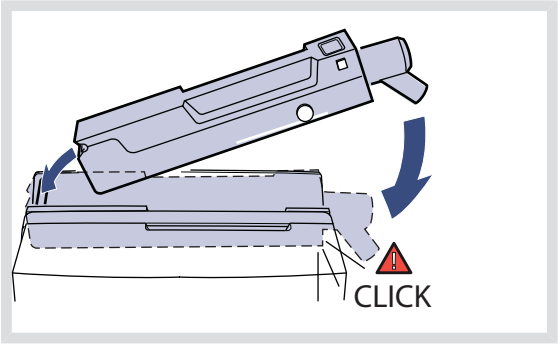
For drying alternatives, see page 18 .

2.6 ASSEMBLING

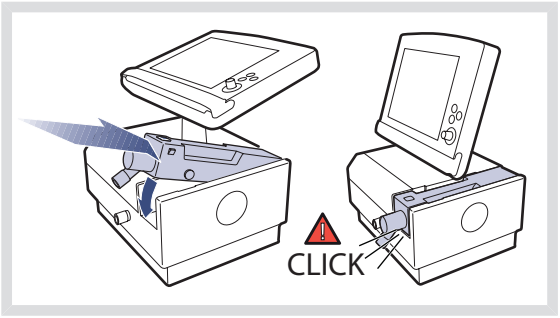


2.6.1 RE-INSERTING THE EXPIRATORY CASSETTE

SERVO-i



SERVO-s



- Hinge the expiratory cassette and press it firmly down into lock position.

WARNING! ⚠ Make sure that the cassette clicks into position. Check that it cannot be moved upwards and that the button on top of the cassette is completely ejected.

- Note on a log sheet that a routine cleaning has been performed. Refer to hospital guidelines.

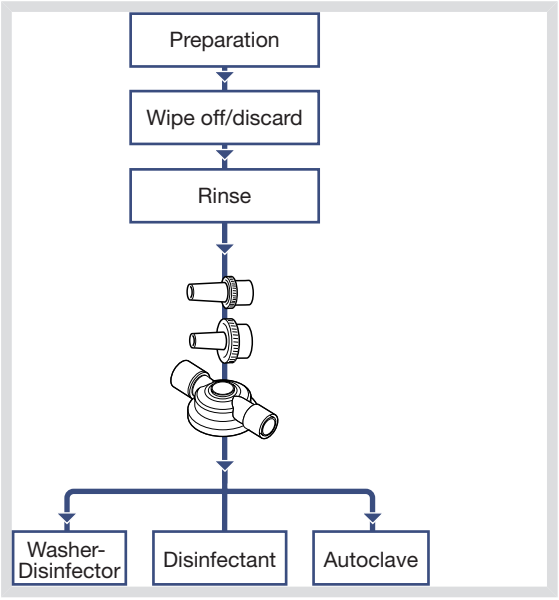
2.6.2 PRE-USE CHECK

After cleaning, always perform a Pre-use check. For more information, please refer to the SERVO-i/s User's Manual.

If the Pre-use check fails:
- Carefully shake/tilt the cassette (5-7 times).
- Run the cassette in a SERVO-i/s ventilator with a test lung for 10 minutes.
- Re-do the Pre-use check.

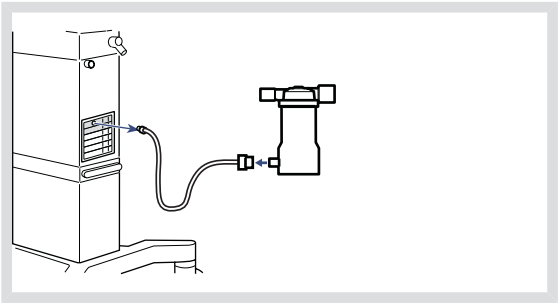
2.7 SERVO ULTRA NEBULIZER CLEANING

- Cleaning should be done after each patient or according to hospital routine.
- Perform a function test of the SERVO Ultra Nebulizer after the cleaning. Refer to the SERVO-i/s User's Manual.



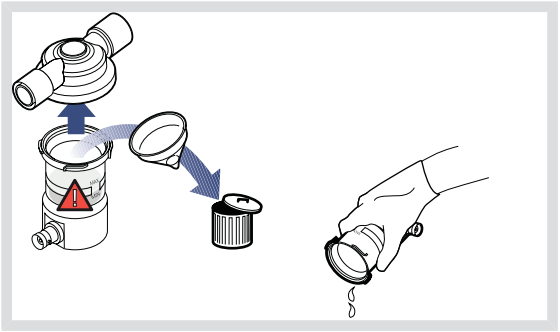
Only the T-piece and nipples can be autoclaved.
The medication cup must not be disposed of with ordinary waste.

2.7.1 PREPARATION



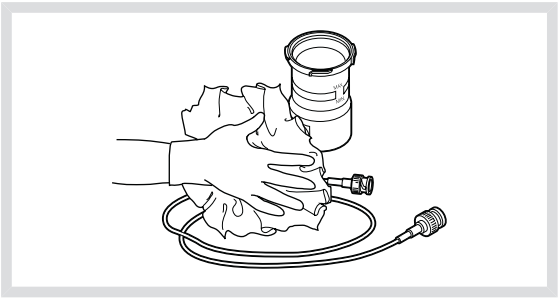
Disconnect the Servo Ultra Nebulizer from the ventilator.

2.7.2 WIPING AND DISCARDING



- Unscrew the T-piece and discard the medication cup.
- Empty the buffer water from the nebulizing chamber.

IMPORTANT: ⚠ Do not autoclave or use a washer-disinfector when cleaning the nebulizing chamber.



- Wipe the nebulizing chamber and connection cable with a soft cloth moistened in soap & water or detergent-based disinfectant.

Note: In case of more contaminated surfaces, use ethyl alcohol (70%) or isopropyl alcohol (70%).

2.7.3 RINSE

Rinse the parts thoroughly in water (<35°C/95°F).

2.7.4 DISINFECTION PROCEDURE

Washer-Disinfector

Wash the T-piece and nipples in a washer-disinfector at a temperature of 85-95°C (185-203°F).

IMPORTANT: Do not put the nebulizing chamber in a washer-disinfector.

Disinfectant

1. Let the T-piece and nipples soak in a disinfectant such as
- Cidex OPA
- Hexanios G+R
- Aniosyme DD1
- Gigazyme Plus

IMPORTANT: Follow the disinfectant manufacturer's recommendations and instructions.

2. Rinse the T-piece and nipples thoroughly in water (<35°C/95°F).

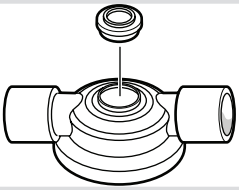
2.7.5 STERILIZATION PROCEDURE

Autoclave

The T-piece and nipples can be autoclaved in a validated process, typically at a temperature of 134°C (273°F) for 4-7 minutes.

IMPORTANT: Do not autoclave the nebulizing chamber.

2.7.6 NEBULIZER MEMBRANE



Replacement of membrane if needed/used:

- Peel off the old membrane.
- Put a new membrane in place.
- Make sure the new membrane is properly attached. This is easiest to see from the inside.
- Check the SERVO Ultra Nebulizer for leakage (Pre-use check, SERVO-i/s User's Manual).

2.8 SERVO-i NAVA SYSTEM CLEANING

2.8.1 WIPING AND DISCARDING

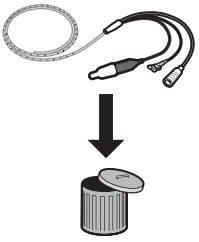
Cleaning should be done after each patient or according to hospital routine.

Wipe all parts with a soft lint-free cloth moistened in soap and water or detergent-based disinfectant.

IMPORTANT: Do not immerse the Edi module or the cable in fluid.

Note: In case of more contaminated surfaces, use ethyl alcohol (70%) or isopropyl alcohol (70%). Avoid contact with electrical contacts.

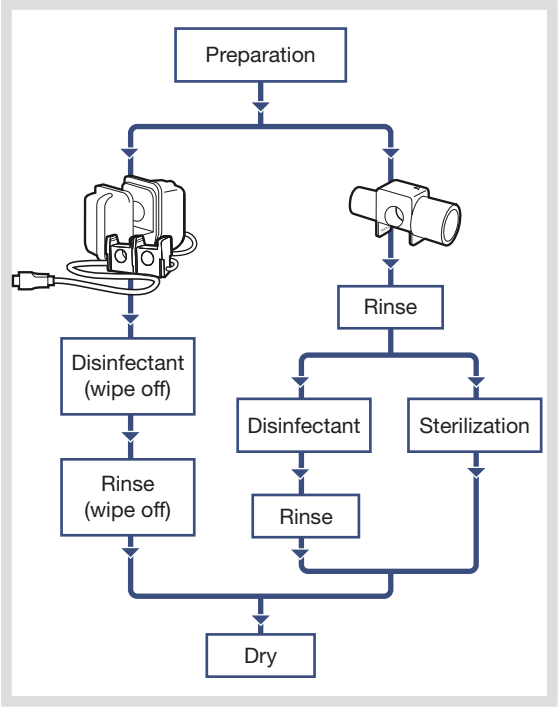
Discard the Edi catheter. The Edi catheter is for single patient use only.



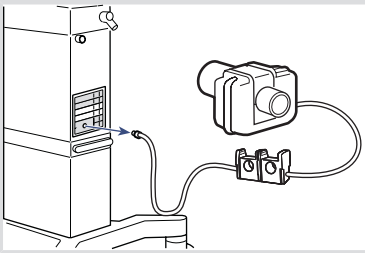
Note: The Edi catheter must not be disposed of with ordinary waste.

2.9 SERVO CO_2 ANALYZER CLEANING

Cleaning should be done after each patient or according to hospital routine.



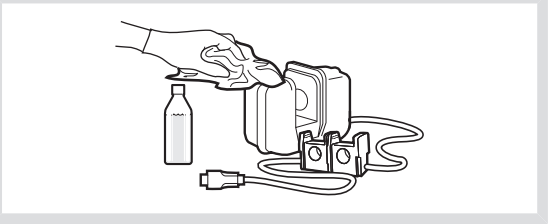
2.9.1 PREPARATION



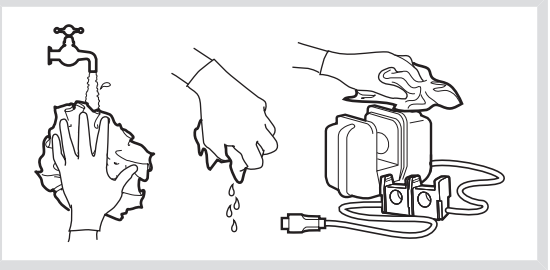
- Disconnect the Capnostat sensor and airway adapter from the ventilator.

2.9.2 CAPNOSTAT SENSOR

Disinfection procedure



- Wipe the Capnostat sensor with a soft cloth moistened in disinfectant (Cidex OPA or isopropyl alcohol 70%).



- After cleaning, wipe the Capnostat sensor with a water-dampened clean cloth.
- The Capnostat sensor windows must be dried after cleaning.

2.9.3 AIRWAY ADAPTER

The airway adapter can be disinfected or sterilized.

- Rinse the adapter thoroughly in water (<35°C/95°F).

IMPORTANT: Do not immerse the CO_2 analyzer module or the Capnostat sensor in fluid.

Disinfection procedure

- Let the adapter soak in Cidex OPA solution.
- Rinse the adapter thoroughly in distilled water.
- Before reusing the adapter, the windows must be dry and wiped off.

IMPORTANT: Follow the disinfectant manufacturer's recommendations and instructions.

Sterilization procedure

- The adult adapter can be autoclaved in a validated process, typically at a temperature of 134°C (273°F) for 4-7 minutes.
- The neonate and adult adapters can be sterilized using EtO (ethylene oxide) gas method.
- After sterilization procedure the adapters must be dried before use.

2.10 ACCESSORIES

Fischer & Paykel Humidifier MR850

Refer to the cleaning routines in the operating manual for the Fischer & Paykel Humidifier.

Aeroneb-Pro (Aeroneb Professional Nebulizer system)

Refer to the cleaning routines in the operating manual for the Aeroneb-Pro (Aeroneb Professional Nebulizer system).

3 MAINTENANCE

TABLE OF CONTENTS

3.1	Preventive maintenance	28
3.2	O_2 sensor	28
3.3	O_2 cell	28
3.4	Extended cleaning of inspiratory channel	32
3.5	Accessories	35

3.1 PREVENTIVE MAINTENANCE

MAQUET recommends that the equipment is inspected regularly.

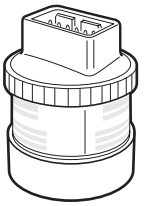
A preventive maintenance, according to corresponding chapter in the Service manual, must be performed by authorized personnel at least once every year as long as the unit is not used more than normal. Normal operation during one year is estimated to correspond to approximately 5000 hours of operation. The current operating time and time to next preventive maintenance is presented under the Status menu on the User Interface.

IMPORTANT: It is recommended that a regular cleaning and an extended cleaning of the inspiratory channel should be performed before carrying out preventive maintenance. The extended cleaning must be done by trained personnel only.

3.2 O_2 SENSOR

No regular maintenance required.

3.3 O_2 CELL



Regularly check the cell status in the *Status* menu. The O_2 cell should be exchanged if <10% estimated remaining capacity is indicated in the *Status* menu. Refer to SERVO-i/s User's manuals for O_2 cell adjustment.

WARNING! The sealed unit of the O_2 cell contains a caustic liquid which may cause severe burns to the skin and eyes. In case of contact, immediately wash the affected area continuously with water for at least 15 minutes and seek medical attention, especially if the eyes are affected.

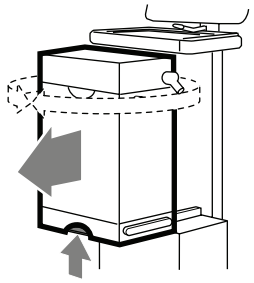
IMPORTANT:

- Make sure the O_2 cell is for the SERVO-i/s models. The O_2 cell package must have a blue label.
- Replacement of the O_2 cell and filter and extended cleaning may only be performed by trained personnel.

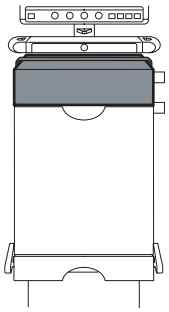
3.3.1 PREPARATIONS AND DISMANTLING

- Unpack the O_2 cell at least 15 minutes before replacement. Turn the ventilator off using the switch on the rear of the user interface.
- Disconnect the ventilator from the power and gas supply.

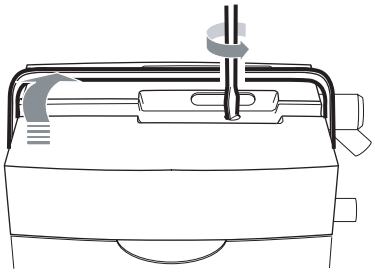
SERVO-i



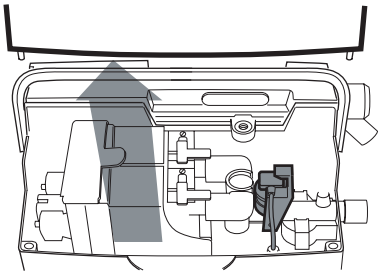
- Lift the locking handle and pull out the patient unit.



- Lift the handle and fold it over the Expiratory cassette.

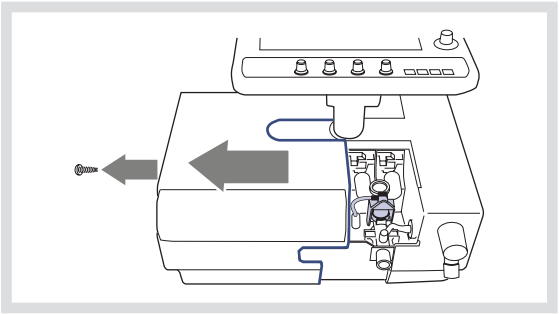


- Turn the bayonet screw one quarter of a turn to release.



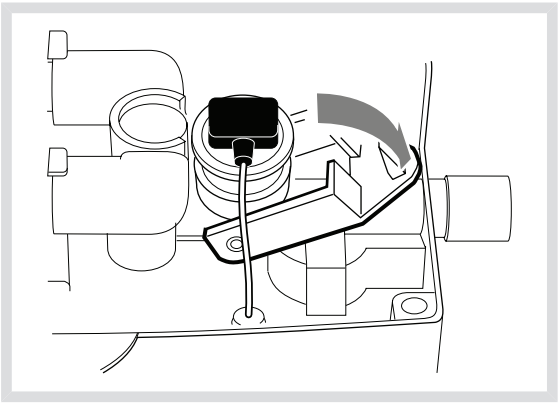
- Lift off the cover.

SERVO-s

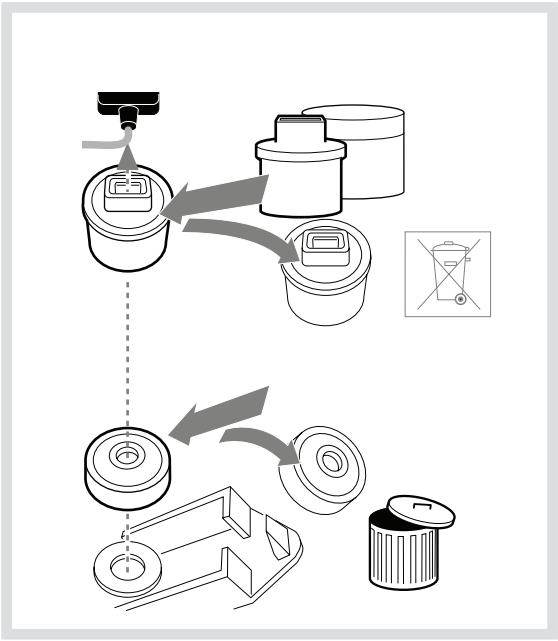


- Loosen the screw.
- Pull out the cover.

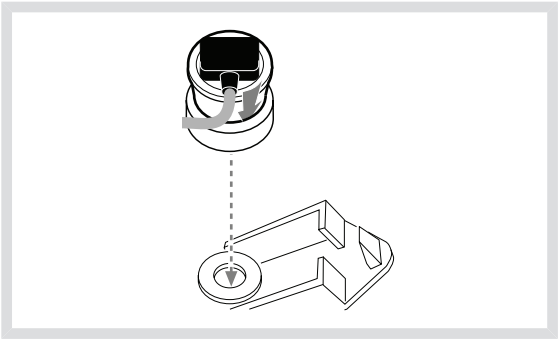
3.3.2 REPLACEMENT OF O_2 CELL AND/OR BACTERIAL FILTER



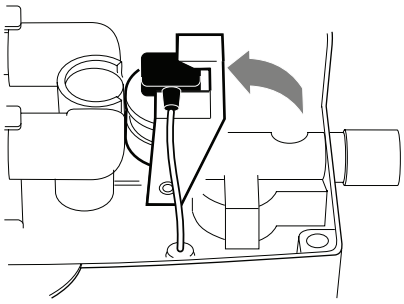
- Lower the locking catch.



- Disconnect the O_2 cell connector.
- Lift and discard the O_2 cell with the rubber seal to special waste and/or remove and discard the bacterial filter to hazardous waste.



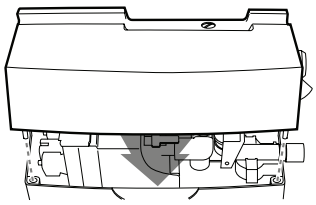
- Ensure that the new rubber seal is intact, then firmly put in a new bacterial filter.



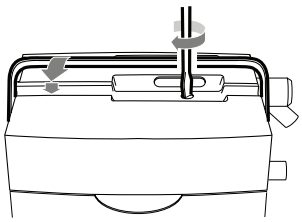
- Connect the O_2 cell connector.
- Put the O_2 cell in position.
- Close the locking catch.

3.3.3 ASSEMBLING

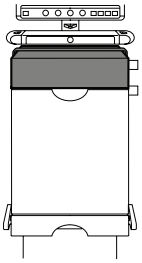
SERVO-i



- Put the cover in position.

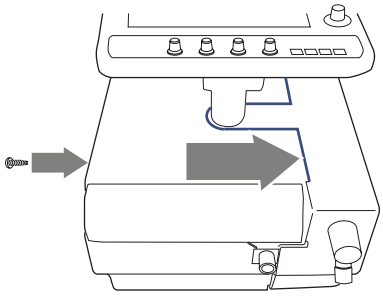


- Tighten the bayonet screw.



- Angle up the handle and push it down in position.
- Perform a Pre-use check, see SERVO-i User's Manual.

SERVO-s



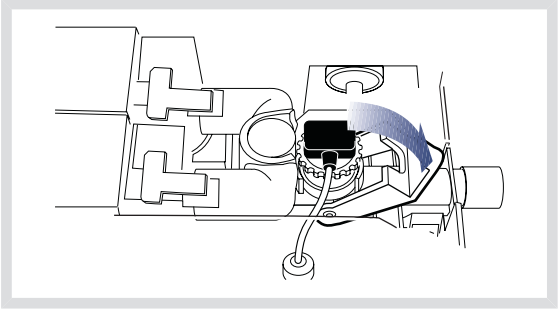
- Push the cover in position.
- Tighten the screw.
- Perform a Pre-use check, see SERVO-s User's Manual.

3.4 EXTENDED CLEANING OF INSPIRATORY CHANNEL

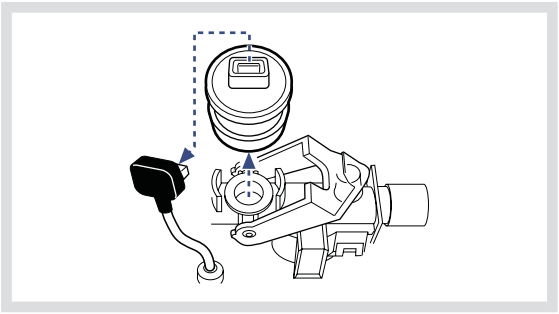
3.4.1 PREPARATIONS AND DISMANTLING

Follow the instructions for preparation and dismantling as given on page 29.

O_2 cell is installed

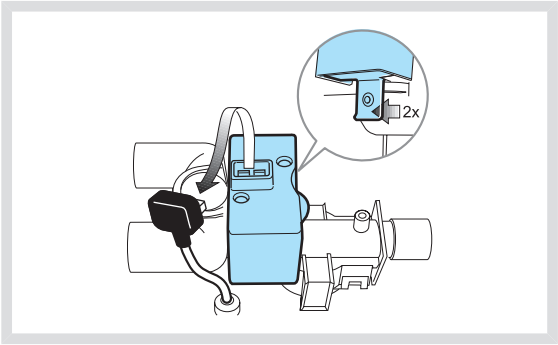


- Lower the locking catch.

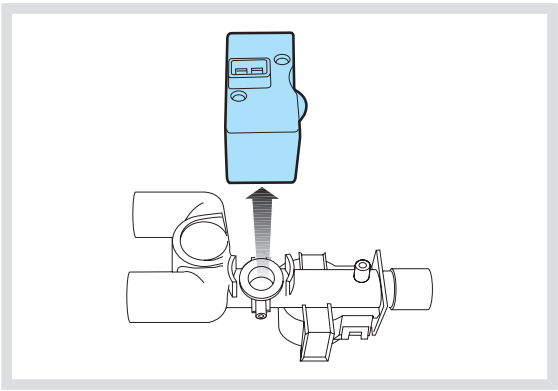


- Disconnect the O_2 cell connector and lift out the O_2 cell.

O_2 sensor is installed

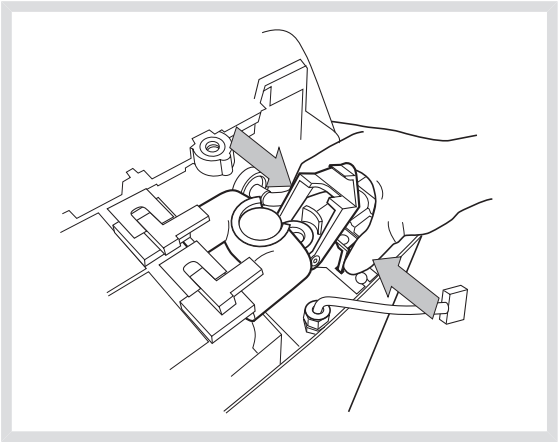


- Disconnect the O_2 sensor and carefully unlock the latches.



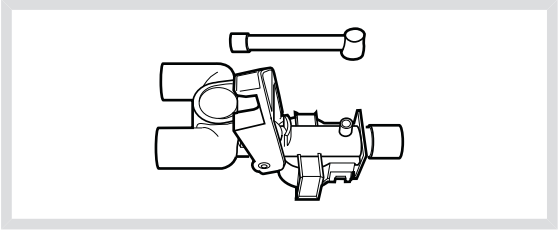
- Lift the O_2 sensor out of position.

3.4.2 REMOVE THE INSPIRATORY CHANNEL AND TUBE



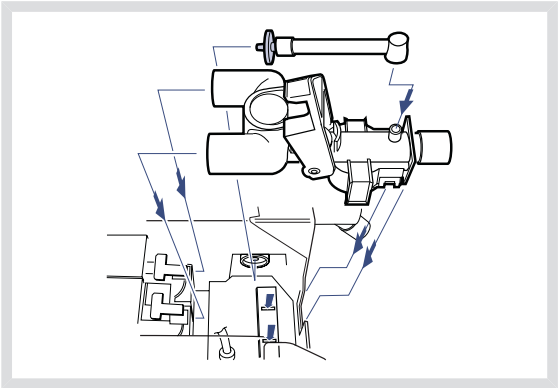
- Press the latches and lift the inspiratory channel upwards. Disconnect the connector muffs.
- Disconnect the tube and remove the bacterial filter. Discard the filter to hazardous waste.

3.4.3 DISINFECTION/STERILIZATION PROCEDURES

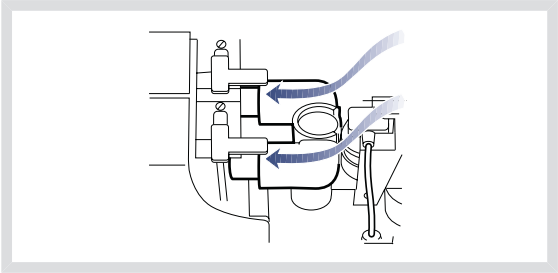


Clean the inspiratory channel and tube the same way as the expiratory cassette. See page 9.

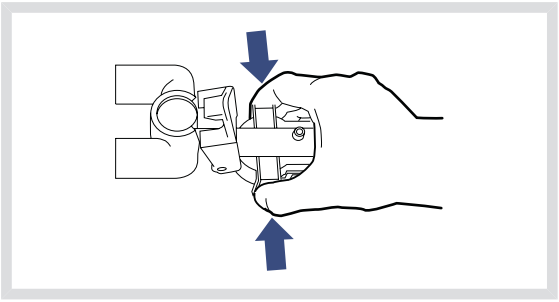
3.4.4 INSERT THE INSPIRATORY CHANNEL AND TUBE



- Put a new bacterial filter in position and connect the filter to the tube.



- Put the connector muffs in position.

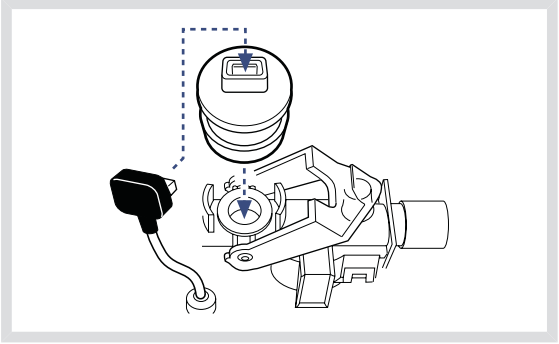


- Press the latches and insert the inspiratory channel.

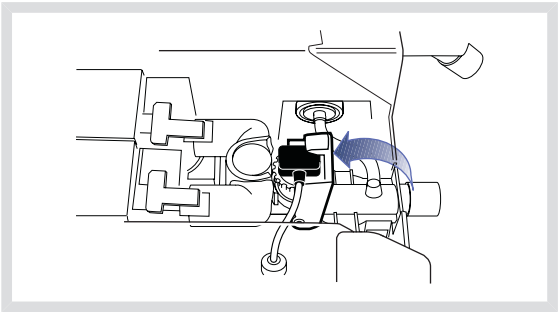
IMPORTANT:
- There should always be clearance between the connector muffs and gas modules.
- Make sure the latches are locked in position.

3.4.5 INSERT THE O_2 CELL/O_2 SENSOR

Insertion of O_2 cell

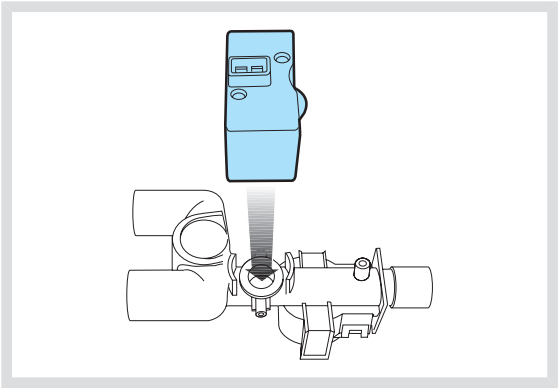


- Connect the O_2 cell connector and put the O_2 cell in position.

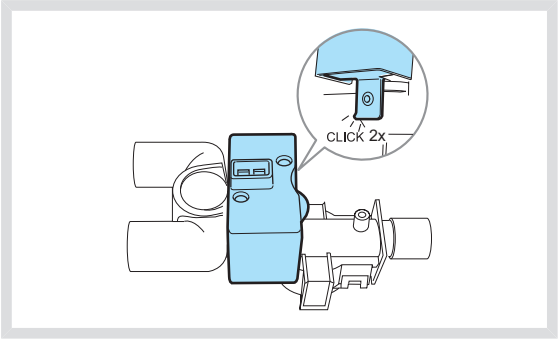


- Close the locking catch.

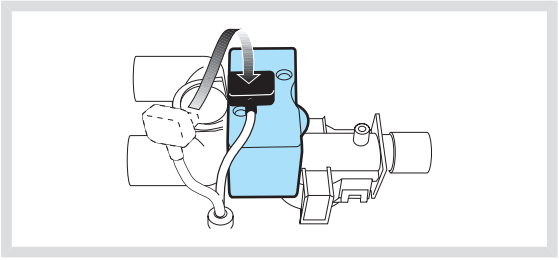
Insertion of O_2 sensor



- Put the O_2 sensor in position.



- Connect the O_2 sensor (two "clicks" are heard).



- Connect the O_2 sensor connector.

3.4.6 ASSEMBLING

- Re-assemble according to instructions given on page 31.
- Note on a log sheet that an extended cleaning of the inspiratory channel has been performed.
- Perform a Pre-use check (see SERVO-i/s User's Manuals).

IMPORTANT: The accuracy of the measurement is dependent of the quality (oxygen content) of supplied gases during Pre-Use Check.

3.5 ACCESSORIES

Fischer & Paykel Humidifier MR850 (optional)

Refer to the operating manual for the Fisher & Paykel Humidifier MR850.

Aeroneb Professional Nebulizer System (optional)

Refer to the operating manual for the Aeroneb Professional Nebulizer System.

Disposable parts

Use disposable and spare parts from MAQUET only. All disposable parts must be discarded according to hospital routine and in an environmentally safe way.

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